DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

EOS Imaging
% Mr. John J. Smith
Regulatory Counsel
Hogan Lovells US L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

January 22, 2015

Re: K142773
Trade/Device Name: EOS System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: December 12, 2014
Received: December 12, 2014

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142773

Device Name
EOS System

Indications for Use *(Describe)*
EOS is intended for use in general radiographic examinations and applications, excluding the evaluation of lung nodules and examinations involving fluoroscopy, angiography, and mammography. EOS allows the radiographic acquisition of either one or two orthogonal X-ray images for diagnostic purposes, in one single scan, of the whole body or a reduced area of investigation of a patient in the upright or seated position.

The Micro Dose feature is indicated for imaging with a patient entrance dose of 10 to 90 μGy for assessing global skeletal deformities in follow-up pediatric examinations. Micro Dose is not indicated for focal skeletal abnormalities and/or other pediatric abnormalities. Micro Dose is not indicated for use in patients with a Body Mass Index over 30.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

EOS imaging's EOS System

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FRANCE

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Contact Person: Karine Chevrie, Quality and Regulatory Affairs Officer

Date Prepared: January 22, 2015

Name of Device and Name/Address of Sponsor:

EOS System
EOS imaging
10 rue Mercoeur
PARIS F-75011
FRANCE

Common or Usual Name: Digital Radiography System

Classification Regulation: 21 C.F.R. § 892.1680; Stationary X-Ray System
Product Code KPR – System, X-Ray, Stationary

Predicate Devices: EOS imaging's EOS (K123740)

Intended Use/ indication for use

EOS is intended for use in general radiographic examinations and applications, excluding the evaluation of lung nodules and examinations involving fluoroscopy, angiography and mammography. EOS allows the radiographic acquisition of either one or two orthogonal X ray images for diagnostic purposes, in one single scan, of the whole body or a reduced area of investigation of a patient in the upright or seated position.

The Micro Dose feature is indicated for imaging with a patient entrance dose of 10 to 90 µGy for assessing global skeletal deformities in follow-up pediatric examinations. Micro Dose is not indicated for focal skeletal abnormalities and/or other pediatric abnormalities. Micro Dose is not indicated for use in patients with a Body Mass Index over 30.

Technological Characteristics

EOS is a digital radiography system in which two sets of xenon gas filled digital detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. A new acquisition feature named Micro Dose allows image acquisition with a patient entrance dose of 10 to 90 µGy for assessing global skeletal deformities in follow-up pediatric exams. The diagnostic images are stored in a local

database and are displayed on a high-resolution, medical-quality monitor, where the diagnosis is performed. The diagnostic image can be transmitted through a DICOM 3.0 compatible digital network for printing and archiving.

Performance Data

The company's performance testing was designed to confirm performance of the EOS System at a dose level used by the Micro Dose feature. Performance testing included safety testing according to IEC, image quality bench testing, and clinical testing. The objective of these performance tests was to confirm the ability of the EOS System's Micro Dose acquisition feature to generate very low X-ray dose images allowing for the follow-up assessment of global skeletal deformities in pediatric patients. The Micro Dose image quality was assessed by: (1) rating the visibility of the anatomical landmarks used for the measurement of the clinical parameters for spine scoliosis follow up; and (2) assessing the reproducibility and the accuracy of the measurements of clinically relevant scoliosis angles. Based on the results of these performance tests it was concluded that the Micro Dose feature enables the analysis of global skeletal deformity in the context of radiographic examinations which do not require fine bone structure analysis, such as follow-up exams of the spine or lower limb. In such exams, the patient entrance dose of 10 to 90 µGy associated with the Micro Dose feature is an advantage, especially in pediatric patients who are more susceptible to radiation.

Substantial Equivalence

The EOS is essentially the same device as its predicate device with the exception of the revised indications for use that includes the indication for use of the Micro Dose acquisition protocol, which is more specific compared to the indication for use of higher X-ray dose acquisition settings. The Micro Dose feature is indicated for imaging with a patient entrance dose of 10 to 90 µGy for assessing global skeletal deformities in follow-up pediatric examinations. This change does not alter the device's diagnostic effect, and performance testing demonstrates safety and performance comparable to the predicate. Thus, the EOS is substantially equivalent to the predicate device.